IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re application of:	Confirmation No: 2553
Alexander MacGREGOR	Attorney Docket No: 026806.00017
Serial Number: 10/006,740	Group Art Unit: 1618
Filed: December 5, 2001	Examiner: Blessing M. FUBARA

For: HYDROSTATIC DELIVERY SYSTEM FOR CONTROLLED DELIVERY OF AN AGENT

PRE-APPEAL BRIEF REQUEST FOR REVIEW

Commissioner for Patents
P.O. Box 1450
Alexandria, Virginia 22313-1450

Date: January 24, 2008

Sir:

In response to the Final Office Action mailed December 5, 2007 Applicant respectfully submits that the Office Action is both factually and legally incorrect, and hereby submits this Pre-Appeal Brief Request for Review. This request is not accompanied by an amendment to the currently pending claims, and is being filed with a Notice of Appeal.

Claims 47-74 are pending in the subject application, with claims 47, 54, 56, 61, 68, and 70 being independent. The outstanding Office Action is the eighth Office Action in this application. This application qualifies for Appeal.

The outstanding Office Action rejected claims 55 and 69 under 35 U.S.C. § 112, first paragraph, as allegedly lacking support in the written description. Claims 47, 50-53, and 56-60 were rejected under 35 U.S.C. §102(b) as allegedly being anticipated by U.S. Patent No. 5,357,636 (Dresdner, Jr. et al.). Claims 47, 49-55, and 61-69 were rejected under 35 U.S.C. §102(b) as allegedly being anticipated by U.S. Patent No. 5,840,329 (Bai). Claims 47-58 and 61-74 were rejected under 35 U.S.C. §103(a) as allegedly being unpatentable over U.S. Patent No. 5,582,838 (Rork et al.) and U.S. Patent No. 5,780,057 (Conte et al.). Claims 47 and 50-74 were rejected under 35 U.S.C. §103(a) as allegedly being unpatentable over Dresdner, Jr. et al. and U.S. Patent No. 6,071,539 (Robinson et al.).

Applicant respectfully traverses the outstanding rejections, and submits that they were made in error for at least the reasons set forth below.

I. Rejection under 35 U.S.C. § 112

Claim 55 and 69 were rejected under 35 U.S.C. § 112, first paragraph, on the grounds that the feature wherein the dosage forms of the claimed invention include an outer coating that may be selected from "hydrosoluble polymers" was not adequately disclosed in the specification. *See* page 2, paragraph 2 of the Office Action. Applicant submits that this feature is disclosed in the specification at least at paragraphs [0125] and [0130], which indicate that the dosage forms may be coated with a non-functional coating, such as a hydrosoluble polymer, for aesthetic reasons. One skilled in the art at the time the present invention was made would be readily able to select appropriate hydrosoluble polymers using the guidance provided in the specification. Applicant respectfully requests withdrawal of this rejection.

II. Essential Elements are Not Disclosed by the Cited References

In the outstanding Office Action, the Examiner has cited references that do not disclose or suggest all of the claimed features.

Applicant respectfully submits that none of the cited references disclose or suggest dosage forms ***consisting of a compressed, homogeneous mixture of a pharmacologically-active substance and a hydrostatic couple***, or capsule dosage forms including ***a homogeneous mixture of a plurality of compressed particles, each particle consisting of a mixture of a hydrostatic couple and a pharmacologically-active substance***. Support for these dosage forms may be found in Applicant's specification as set forth in the September 6, 2007 Amendment on page 12. These unique hydrostatic dosage forms provide controlled release of an agent of interest using non-osmotic hydrostatic differential pressure.

A. Rejections over Dresdner, Jr. et al., optionally in view of Robinson

Dresdner, Jr. et al. relates to a flexible glove including an antiseptic composition provided between inner and outer glove layers. The antiseptic composition may include various ingredients, such as Carbopol (which is an acrylic acid polymer cross-linked with allylsucrose or allylpentaerythritol), cross-linked polyvinylpyrrolidone, sodium perborate, and sodium hypochlorite. The antiseptic compositions could not be compressed without

rendering the glove unsuitable for its intended use, *i.e.*, providing first order release of an antiseptic composition if the glove is punctured while being worn.

Robinson et al. relates to effervescent granules including an acidic agent, an alkaline agent, a hot-melt extrudable binder, and optionally a plasticizer. The granules are prepared by hot-melt extrusion. Although the granules may be combined with an active agent to form a dosage form, they do not generally include therapeutic compounds or other active ingredients. (*See* col. 3, lines 1-9.) The effervescent granules of Robinson et al. are apparently cited only for the fact that they can be provided as a tablet or capsule.

Mere inclusion of a few similar ingredients in the disclosures of Dresdner, Jr. et al. and Robinson et al. does not establish that they disclose ***dosage forms for oral administration*** that ***consist of a compressed, homogeneous mixture of a pharmacologically-active substance and a hydrostatic couple***, or a capsule containing a ***homogeneous mixture of a plurality of compressed particles, each particle consisting of a mixture of a hydrostatic couple and a pharmacologically-active substance***. In fact, there is absolutely no teaching whatsoever in Dresdner, Jr. et al. or Robinson et al. of anything in any way applicable to hydrostatic delivery systems, or anything in any way related whatsoever to the claimed invention. It appears that Dresdner, Jr. et al. was cited only because it was found in a word search for Carbopol and PVP, with no appreciation for the use of these ingredients that was being made in that reference. Robinson was cited only because it discloses providing its components within a capsule or tablet, without regard to the features of the claimed invention.

Accordingly, Applicant respectfully submits that Dresdner, Jr. et al. does not anticipate claims 47, 50-53, and 56-60, and that claims 47 and 50-74 are not obvious in view of Dresdner, Jr. et al., in view of Robinson et al. As such, the Applicants submit that claims 47 and 50-74 are allowable over Dresdner, Jr. et al. and Robinson et al.

B. Rejection over Bai

Bai relates to a pulsatile drug delivery system including a plurality of particles having multi-layer cores formed from a controlled release matrix including a water-insoluble poly(acrylic acid) and a water-soluble polymer or monomer, which may include a medicament. The water-soluble polymer or monomer of the controlled release matrix may include non-crosslinked PVP. A swelling layer may include crosslinked PVP or crosslinked

cellulose as swelling agents. An external coating layer is required, which includes water-insoluble, water-permeable polymer and water-insoluble, water-swellable polymer, and a water-permeation adjusting agent. The pulsatile delivery system of Bai includes non-homogeneous, multilayered particles, and Bai does not disclose ***dosage forms for oral administration*** that ***consist of a compressed, homogeneous mixture of a pharmacologically-active substance and a hydrostatic couple***, or a capsule containing a ***homogeneous mixture of a plurality of compressed particles, each particle consisting of a mixture of a hydrostatic couple and a pharmacologically-active substance***. The pulsatile delivery system could not be modified so that the particles are homogeneous without rendering the delivery system unsuitable for its intended use, *i.e.*, providing pulsatile release of an active agent.

Accordingly, Applicant respectfully submits that Bai does not anticipate claims 47, 49-55, and 61-69, and that claims 47, 49-55, and 61-69 are not obvious in view of Bai. As such, the Applicants submit that claims 47, 49-55, and 61-69 are allowable over Bai.

C. Rejection over Rork et al. and Conte et al.

Rork et al. relates to a multi-layer tablet composition including a single core comprising at least two layers, where one layer includes an active agent and a polymer that forms microscopic gel beads when hydrated, and a second layer that includes a polymer that forms microscopic gel beads when hydrated. An impermeable coating adheres to and surrounds the core, and contains apertures that provide an area for hydration and release of the microscopic gel beads.

Conte et al. relates to a multi-layer tablet composition including at least two layers, where at least one layer contains a polymer that rapidly swells on contact with fluids, thereby increasing tablet volume, and another layer contains the active ingredient and optionally polymeric substances. The swellable layer and an optional third layer may be impermeable to the active agent, and may form barriers to modulate release of the active agent.

The Examiner has indicated in the Response to Arguments section of this rejection that the tablet of the claimed dosage form does not exclude layered tablets. However, Applicant respectfully disagrees with this position, as both Rork et al. and Conte et al. explicitly indicate that they require at least two layers, while the presently-claimed invention

consists of *a compressed, homogeneous mixture of a pharmacologically-active substance and a hydrostatic couple*, or *a homogeneous mixture of a plurality of compressed particles, each particle* ***consisting of*** *a mixture of a hydrostatic couple and a pharmacologically-active substance*. The "consisting of" and "homogeneous" language of the claims excludes the possibility of layered tablets, and Rork et al. and Conte et al. explicitly exclude dosage forms including only a single, homogeneous layer.

In view of the above, Applicant respectfully submits that Rork et al. and Conte et al., alone or in combination, fail to disclose or suggest all the features of the pending claims. The Office Action has failed to establish a *prima facie* case of obviousness for purposes of a rejection of claims 47-58 and 61-74 under 35 U.S.C. § 103(a). As such, Applicant submits that claims 47-58 and 61-74 are allowable over Rork et al. and Conte et al.

III. Conclusion

For all of the above reasons, a favorable decision and allowance of all pending claims are earnestly solicited.

In the event this paper is not considered to be timely filed, Applicant respectfully petitions for an appropriate extension of time. Any fees for such an extension, together with any additional fees that may be due with respect to this paper, may be charged to counsel's Deposit Account No. 01-2300, **referencing Attorney Dkt. No. 026806.00017**.

Respectfully submitted,

Dawn C. Russell
Attorney for Applicant
Registration No. 44,751

Customer No. 004372

ARENT FOX LLP
1050 Connecticut Avenue, N.W., Suite 400
Washington, D.C. 20036-5339
Tel: (202) 857-6000
Fax: (202) 638-4810

Enclosures: Notice of Appeal (Form PTO/SB/31)
Pre-Appeal Brief Request for Review (Form PTO/SB/33)

Doc Code: AP.PRE.REQ

PTO/SB/33 (07-05)
Approved for use through xx/xx/200x. OMB 0651-00xx
U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE
Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it displays a valid OMB control number.

PRE-APPEAL BRIEF REQUEST FOR REVIEW

Docket Number (Optional): 026806.00017

I hereby certify that this correspondence is being deposited with the United States Postal Service with sufficient postage as first class mail in an envelope addressed to "Mail Stop AF, Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450" [37 CFR 1.8(a)]

on _____

Signature _____

Typed or printed name _____

Application Number	Filed
10/006,740	12/05/2001

First Named Inventor: Alexander MacGREGOR

Art Unit	Examiner
1618	B. Fubara

Applicant requests review of the final rejection in the above-identified application. No amendments are being filed with this request.

This request is being filed with a notice of appeal.

The review is requested for the reason(s) stated on the attached sheet(s).
Note: No more than five (5) pages may be provided.

I am the

☐ applicant/inventor.

☐ assignee of record of the entire interest.
See 37 CFR 3.71. Statement under 37 CFR 3.73(b) is enclosed.
(Form PTO/SB/96)

☑ attorney or agent of record.
Registration number 44,751.

☐ attorney or agent acting under 37 CFR 1.34.
Registration number if acting under 37 CFR 1.34 _____

George E. Grandjean 27931
Signature

Dawn C. Russell
Typed or printed name

202-857-6000
Telephone number

January 24, 2008
Date

NOTE: Signatures of all the inventors or assignees of record of the entire interest or their representative(s) are required.
Submit multiple forms if more than one signature is required, see below*.

☑ *Total of 1 forms are submitted.

This collection of information is required by 35 U.S.C. 132. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.11, 1.14 and 41.6. This collection is estimated to take 12 minutes to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. **SEND TO: Mail Stop AF, Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.**

If you need assistance in completing the form, call 1-800-PTO-9199 and select option 2.